In The Matter Of :

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
SCIENCE ADVISORY BOARD

LIBBY AMPHIBOLE ASBESTOS REVIEW PANEL MEETING - DAY 1

February 6, 2012

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Monday, February 6, 2012

(Transcript with Revised Corrections After Review of Counsel, July 2012)

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DR. KANE: Does anyone at EPA have a clarification here? I think it's important that we discuss the hazard identification issues first before we go into the details of non-cancer versus cancer health effects.

DISCUSSION ON CHAPTER 4

DR. NEWMAN: Well, I'm fine with if you want me to with diving into this first, you know, this 2.A.1 question. Would that be helpful if we just go to that?

So, okay, you know my comments overall in terms of, you know, the selection of the Marysville, Ohio facility for the derivation of the RfC is that overall that worker cohort provides in my opinion sufficient basis for the derivation of the RfC despite some of the limitations.

And I know, Dr. Peto, we are going to have to come back and talk to your question at some point, but just to kick it off I think it's noted in the draft review there are -- there is uncertainty in terms of the exposure data prior to 1973 and that it could lead just in potential underestimates of

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exposure.

And, but along with the cohort's potential biases, it's important that the RfC account for this uncertainty and also for the fact that this cohort is not representative of the general population. I think that has to be taken into account here. It's almost all -- it's all adult. It's 94 percent male. It's Caucasian. Nevertheless, the data are robust in that they include individual measurements on smoking, BMI, sex, age, hire date.

The size of the cohort are reduced over time, and so participation bias is important to consider because it could lead to an underestimation of risk. And, but they do address those issues in this draft.

Now, so I think that overall, like I said, Marysville, Ohio would be sufficient basis. However, and I don't know when we are going to get a chance to review those other papers that we've asked for, but my recommendation would be that the EPA consider inclusion of the Minneapolis expoliation community cohort in calculating this RfC.

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And the basis for that is that the -- that group does provide opportunity to look at a potential health impact at exposure levels that are lower than those that are indicated in the Marysville cohort, at least that's my reading of it. So I think it's important that this additional community cohort be considered in deriving the RfC. It probably would be the basis of a LOEL.

That cohort, for people that haven't had a chance to read that yet, consisted of 461 nonworkers including women and children. So it's probably more representative of the general population than the Marysville cohort is. Pleural abnormalities were seen at exposures to lower concentrations of Libby amphibole asbestos than in Marysville.

The exposures -- someone asked about this this morning, and I think some of this is in Dr. Adgate's public comments that he submitted, but the exposures there as a point of reference ranged from 0.096 to 5.76 fibers per cc years. And so they are modeled at the low end of the exposures for the Marysville worker cohort.

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The -- and so there were some potential disadvantages which I think the EPA has to take into account when they look at that additional cohort in terms of some of the uncertainty in modeled ambient air concentrations, but I think that the studies do provide individual level modeled exposures. And, therefore, that would be my other comment.

So in sum, okay, I'm okay with Marysville, Ohio. I would recommend that the EPA take the time to look at the -- include the Minneapolis expoliation group as well.

DR. KANE: Dr. Woskie, would you like to add some comments please?

DR. WOSKIE: I would tend to agree with that. And I also would like to have an opportunity to look at the Neil Larsen study as well because I think this goes to the point made by the National Academy of Science in that really sort of bringing more weight of the evidence approach to this question rather than being so focused on one subcohort of one study.

DR. REDLICH: The Marysville cohort doesn't have PFT data. Is that correct?

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DR. KANE: Does Marysville have (inaudible).

DR. DeVONEY: In 1980 they did spirometry, but it's not in their paper. For the 2008, they don't have it. Dr. Lockey and coworkers have done examinations of follow up. He submitted as public comments a one-page table of two publications on the verge, they might even be electronically available within weeks, and then the schedule of how they are going to analyze the data for the next 18 years to two months (sic).

We made a point to get that information for you to look at, and that includes spirometry data. I would also note that Ted Larsen has -- as I found out at lunch will be electronically available in days, perhaps weeks. He's already proved the proofs. A relationship between spirometry and LPT in workers x-rayed in 2000 and 2001 with an odds ratio of 1.4 from 1.1 to one-point something else. And that's in an abstract that we can provide you. But that publication will be available electronically within days.

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So there are some data that will be out very soon. And in his Larsen article that you mentioned, ma'am, he does look at spirometry in that. So that's an available endpoint from that paper that we did not have in our hands before we went to publication.

DR. KANE: Thank you very much for that new information. And is there a general consensus right now that we maybe charge these subgroup leaders with really following up on these publications or preprints, whatever is available, and take that into account in your written report before you submit it back to Diana, in the spirit of the breadth of evidence that the national science -- National Academy of Science want us to go to.

DR. PETO: How does that work if we are looking at that paper, the subgroup is looking at papers that the rest of the group hasn't looked at or evaluated both in terms of most significant endpoint, you know, is this good rationale for this and also the actual RfC?

DR. VU: Agnes, I think before lunch break

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we did ask the agency to provide all the relevant studies that you all asked for which is published beyond the agency's draft report. Those studies have to be made available for the entire panel.

Certainly the subgroup should have the lead in looking closely at analysis, but everything that the SAB considered has to be in the public forum. And, in addition, I hope these publications are peer review published literature so it's not raw data analysis. So hopefully you have all of that.

So the question for EPA folks is are we going to be able to have that during this meeting or we just have to have a subsequent teleconference call for the whole panel to discuss the -- to allow more time for the panel members to digest the studies.

DR. DeVONEY: In terms of making electronic copies available, as I understand it we can share EPA copies with the committee without the copyright issue, is that correct, like we do the Hero links?

Anyway, that being resolved, I think it might be impractical to go out and make xerox copies at the moment. I could make CDs and bring them to you

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in the morning. I can also give them to Dr. Wong to provide to you. Whether she does that via the web site or some other mechanism, I don't know.

With exception of the Marshand paper unless, Dr. Winn, do you have that?

FEMALE SPEAKER: I don't have it with me but I can get it.

DR. DeVONEY: Okay. So I think we are covered on that. Would a CD in the morning work for you or do you want hard copies? Just let me know.

DR. WALKER: If you can get it on the web site, we can just download it directly.

DR. DeVONEY: Okay. I'll coordinate with Diana either at break or after lunch. And, Dr. Kane, just let us know in what format you would like it provided. We have electronic copies of it all.

DR. KANE: What would everyone like? Electronic copies? Is that okay? Okay. Thank you very much.

I didn't mean to exclude the rest of the committee from reviewing those papers. I was deferring to your expertise of the subgroup for the

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really careful analysis. Everyone is actually invited to weigh in.

DR. VU: I just want to clarify my points earlier is that this draft the agency has not considered those studies. So one of the things that you could recommend to the agency whether they should consider or not, certainly the draft assessment should have the current information, but whether you would recommend the agency to initially consider this.

You are not asked to analyze and come up with a reference concentration. You advise the agency what needs to be done. Thank you.

DR. NEWMAN: That's good news.

(Laughter)

DR. KANE: All right. This is a large subgroup, so I would like to invite Dr. Kriebel. Comments?

DR. KRIEBEL: Thank you. Yeah, I actually don't think I have much to say at this point. Because I really need to hear a little bit more.

I think specifically one of the things that's happening here that for me is useful is trying

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to think about how -- one of the things I'm hearing here is a concern of the committee to try and find ways to bring in -- to suggest to EPA how to bring in additional information that may be supportive of an RfC without necessarily completely changing the original strategy.

So, for example, these community exposure studies, there's this concern that by focusing only on the subgroup that's got the really good exposure data, we lose a lot of the larger cohort. And of course that is a concern. Doesn't mean that we should -- I wouldn't necessarily recommend that they throw out what they have done and start over, but I'm looking for ways to suggest that the approach can be strengthened.

And I really don't have anything specific yet because I need to hear a little bit more about this issue of the non-cancer endpoint. So nothing more for now.

DR. KANE: Would anyone else like to add something along those lines? Yes, Julian.

DR. PETO: At the risk of repeating myself,

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I mean a reality check on the appropriateness of the modeling for pleural thickening is as I said this morning, there's a 500-fold difference in the predicted prevalence of pleural thickening compared with the mesothelioma. And in Britain we've actually got data on this but, I mean, roughly one in a thousand British women die of mesothelioma.

There are 300,000 deaths a year, and there's the order of 300,000 deaths in Britain. So one in a thousand British women die of mesothelioma. And there's quite strong evidence that more than half of those are caused by environmental exposure. So this is actually the result of very long-term, low-level asbestos exposure.

And if you multiply 1 in a 1,000 by 500, it would imply that 50 percent of British women have pleural thickening caused by asbestos, which is not the case. And that discrepancy between this modeling and that illustrates how extreme the error is. And I just think it's inappropriate to present these calculations. I think they are -- I think they are completely divorced from reality.

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DR. KANE: All right. So we have that viewpoint on the table. Let's leave it on the table for further discussion.

Lianne Sheppard? You also were involved in this subgroup.

DR. SHEPPARD: Yeah. I don't know that I have too much more to add. I thought that the -- it was the Marysville cohort was well chosen based on the criteria that were used. It would be nice to be able to focus on environmental exposures, but I recognize there really aren't the exposure data except for maybe in this new Minneapolis cohort.

So that would be really great to get the perspective of that. And having more than one study because there's always heterogeneity in estimates, having more than one study so we can get more perspective on these estimates would be great. But given what the EPA had to work with, I think they made very appropriate choices.

DR. KANE: Now, do other members of the panel have any other comments about this, the choice of the study populations particularly? Dr. Salmon?